

## REMARKS

### **1. Claim Rejections -- 35 U.S.C. § 112**

Claims 2, 9 and 12 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office has stated that it is unclear where support comes from the originally filed disclosure for a pre-determined dose of *Morinda citrifolia* that is between two and three ounces. In response, Applicants directs the Office to pages 13 and 15 of the Specification which teach administering *Morinda citrifolia* in concentrations between 2.31 percent and 10 percent two to three times per day. In order for a person to achieve appropriate blood-serum levels when taking *Morinda citrifolia* in this frequency and concentration, a person of average height, weight and metabolism must ingest between two and three ounces of *Morinda citrifolia*.

### **2. Claim Rejections -- 35 U.S.C. § 103**

Claims 1-10, and 12-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,228,491 to Moniz (hereinafter referred to as “Moniz”) in view of WIPO Publication No. WO 01/15553 to Nair et al. (“Nair”) and U.S. Pat. No. 6,254,913 to Wadsworth et al. (“Wadsworth”). Applicants appreciate the concerns raised by the Office, but respectfully submit that in light of the arguments presented below, neither Moniz, Nair, or Wadsworth, either individually or collectively, render the claims of the present invention obvious.

An invention is unpatentable under 35 U.S.C. § 103(a) “if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.”

To establish a *prima facie* case of obviousness, three criteria must be met. “First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *MPEP* § 2142.

### The Moniz Reference

The Office submits Moniz as a reference and claims that the treatment of pain by the action of selective COX-2 inhibition is merely an inherent characteristic of *Morinda citrifolia*. However, Applicants’ claims and disclosure show this is not true.

Applicants claim “varying the concentration” of doses of *Morinda citrifolia* based on several factors in order to limit undesired COX-1 inhibition relative to COX-2 inhibition. *See Claims 1 and 12*. Applicants’ disclosure shows the importance of administering the appropriate concentration of *Morinda citrifolia*. Their experiments showed some concentrations where selective COX-2 inhibition was successfully achieved and other instances where it was not. *See Specification, page 15*. Also, Applicants’ results were not achieved through routine experimentation; rather the results achieved were unexpected and surprising. This is evidenced on page 15 of the Specification where the Applicants describe their findings as follows: “the data suggests the surprising result that in some circumstances ‘less’ *Morinda citrifolia* juice provides ‘more’ inhibition selectivity.”

Thus, the action of selective COX-2 inhibition is not inherent. If it were an inherent characteristic, any concentration of *Morinda citrifolia* would result in the action of selective

COX-2 inhibition because, as an inherent characteristic, it would be part of the “essential character” of *Morinda citrifolia*. See *Merriam-Webster OnLine Dictionary (2003)*. However, this is not the case; Applicants’ disclosure shows that COX-2 selectivity is undermined by excessive, increased concentrations. See *Specification, page 15*. It is only after the inherent COX-1 inhibiting qualities of *Morinda citrifolia* are limited by the methods of the present invention that selective COX-2 inhibition occurs. Consequently, Applicants respectfully request the Office remove its 35 U.S.C. § 103(a) rejection based on Moniz because Moniz neither explicitly, nor implicitly discloses the treatment of pain by the action of selective COX-2 inhibition.

#### The Moniz Reference in Light of the Nair Reference

Applicants respectfully submit it would not be obvious to one of ordinary skill in the art to combine the teachings of Nair with those of Moniz in order to find methods to further investigate the selective COX-2 inhibition. There is no suggestion to combine because, as Applicants’ experiments show, *Morinda citrifolia* relieves pain by at least two methods; one where both COX-2 and COX-1 are inhibited and one where COX-2 is selectively inhibited. The Office has not shown that Nair teaches a method of determining COX-2 selectivity where a fruit extract relieves pain by limiting both COX-2 and COX-1 and by selectively limiting COX-2. As a result, Applicants respectfully request the Office remove its 35 U.S.C. § 103(a) rejection based on Moniz in view of Nair .

#### The Moniz or Nair References in view of the Wadsworth Reference

Because Moniz neither explicitly, nor implicitly discloses the treatment of pain by the action of selective COX-2 inhibition, as described above, the combination of Moniz and Wadsworth fails to teach or suggest all of the claim limitations of the present invention.

Consequently, one of ordinary skill in the art would not be motivated to combine the teachings of Wadsworth with those of Moniz.

In addition, because the Office has not shown that Nair teaches a method of determining COX-2 selectivity where a fruit extract relieves pain by limiting both COX-2 and COX-1 and by selectively limiting COX-2, as described above, the combination of Nair and Wadsworth fails to teach or suggest all of the claim limitations of the present invention. Consequently, one of ordinary skill in the art would not be motivated to combine the teachings of Wadsworth with those of Nair.

In light of the foregoing, as there is nothing in the prior art references that teach or suggest the limitations recited in the claims, Applicants respectfully request that the claims of the application be reconsidered and that the rejection under 35 U.S.C. § 103 be withdrawn.

## CONCLUSION

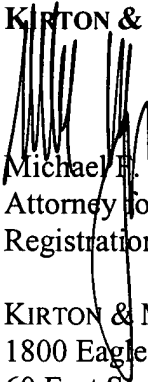
Based on the foregoing, Applicants respectfully submit that the deficiencies in the application have been corrected and that the proposed claims are not rendered obvious by the prior art references cited by the Office. More specifically and as described above, the action of selective COX-2 inhibition is not an inherent characteristic of *Morinda citrifolia*. If it were an inherent characteristic, any concentration of *Morinda citrifolia* would result in the action of selective COX-2 inhibition because, as an inherent characteristic, it would be part of the “essential character” of *Morinda citrifolia*. See *Merriam-Webster OnLine Dictionary (2003)*. However, this is not the case; Applicants’ disclosure shows that COX-2 selectivity is undermined by excessive, increased concentrations. See *Specification, page 15*. It is only after the inherent COX-1 inhibiting qualities of *Morinda citrifolia* are limited by the methods of the present invention that selective COX-2 inhibition occurs. Consequently, Applicants respectfully request the Office remove its 35 U.S.C. § 103(a) rejection based on Moniz in view of Nair and Wadsworth because Moniz neither explicitly, nor implicitly discloses the treatment of pain by the action of selective COX-2 inhibition. As such, Applicants believe that the claims are now in a condition for allowance, and action to that end is respectfully requested.

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Office is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 28 day of October, 2003.

Respectfully submitted,

**KIRTON & MCCONKIE**



Michael E. Krieger  
Attorney for Applicants  
Registration No. 35,232

KIRTON & MCCONKIE  
1800 Eagle Gate Tower  
60 East South Temple Street  
Salt Lake City, Utah 84111  
(801) 328-3600 telephone  
(801) 321-4893 facsimile

BO:

#714554 v1 - Response to 07/28/03 PAT OA